REMARKS

Claims 1-6 and 16-24 are in the case. Applicant hereby affirms the election of graying of scalp hair, pursuant to the requirement noted on page 3 of the Office Action.

Specification

The foregoing Specification amendments are intended to address the trademark usage called to Applicant's attention by the Examiner. The amendments made merely place the trademark usage into USPTO-acceptable form and are otherwise proper.

Rejection

Claims 1-6 and 16-24 stand rejected on the sole ground of obviousness over DeLong et al. (2006/0247214) as evidenced by O'Byrne (Chest, 1997, Vol. 111, No. 2 Supplement, pp 27S-34S), in view of Pizzichini et al. (European Respiratory Journal, 1999, Vol. 14, pp. 12-18) as evidenced by SINGULAIR product information (Merck & Co., Inc., April 2007, pp. 1-19). This rejection is respectfully traversed.

The Examiner's entire rejection of the claims relies upon the erroneous assertion, at page 5 of the Office Action, reading:

> DeLong et al. teach a method for reversing hair graying in mammals comprising administering nonsteroidal anti-inflammatories such as cyclooxygenase or lipoxygenase inhibitors (page 13, paragraph [0110]; and page 14, paragraph [0131]).

When DeLong et al. is carefully read *as a whole*, it is clear that the *prostaglandins*, not any optional anti-inflammatory ingredient, are asserted to prevent graying of hair. See especially in this regard, paragraph [0156] of DeLong et al., which reads:

> [0156] In addition to the benefits in treating hair loss, the inventors have found that the prostaglandins in the compositions and methods of this invention also darken and thicken hair and may reverse hair graying. This invention further relates to a method for darkening hair, thickening hair, and reversing hair graying. The method comprises applying the topical composition for treating hair loss to hair, to skin in the locus of hair, or both. In a preferred embodiment of the

> invention, the topical composition, such as the mascara composition described above, is applied to eyelashes.

The prior paragraph referenced in paragraph 0156 is one of the paragraphs relied upon by the Examiner, namely paragraph 0131. There, it can be seen that nothing in that paragraph suggests that any anti-graying characteristic can be attributed to the optional anti-inflammatory ingredient taught by DeLong et al. In fact, paragraph 0131 suggests that the anti-graying characteristic is universal to any number of the compound ingredient compounds taught by DeLong et al., not only those which have the optional anti-inflammatory ingredient. This all suggests to one of ordinary skill in the art, especially in light of paragraph 156, that the prostaglandin component is responsible for the anti-graying effect asserted to exist in the DeLong et al. invention.

Thus, DeLong et al., when fairly read, cannot be said to teach or even suggest to any person of ordinary skill in the technical field that any lipoxygenase inhibitor would provide any anti-graying attribute to the DeLong et al. compositions. For this reason, the alleged motivation upon which the Examiner's rejection relies on page 6 of the Office Action (reading "Since DeLong et al. teach lipoxygenase inhibitors that control an inflammatory condition such as asthma can also be used to reverse hair graying . . . ") to modify the DeLong et al. teaching does not and cannot in fact exist. In short, the Examiner's conclusion on page 6 that "it would have been obvious to one in the art that montelukast can also be used to reverse hair graying," is unsupported by the actual cited reference.

Accordingly, the central reference upon which the Examiner's rejection relies is not relevant, does not actual provide any of the motivation alleged to exist, and cannot support a *prima facie* case of obviousness in this case. For this reason standing alone, the rejection is improper and should be reconsidered and withdrawn.

Moreover, even if one were to assume *arguendo* that such a motivation could be gleaned from DeLong et al., there is nothing from DeLong et al. which would suggest which of the anti-inflammotory ingredient candidates might be capable of imparting any inhibitory effective on the graying of hair. There is simply no direction given in DeLong et al. about which ingredient, from the sea of ingredient candidates identified, might provide such a feature to the DeLong et al. composition. Furthermore, the montelukast composition is an *oral* pharmaceutical, while the DeLong et al. composition is a *topical* product, and the Examiner cites absolutely nothing which

would suggest that the oral composition could or should be used to modify the DeLong et al. topical composition. Finally, it is also apparent that DeLong et al. refers to "reversing" the gray coloring of hair (presumably which has already turned gray; see DeLong et al., paragraphs 0131 and 0156), rather than *inhibiting* hair graying in the first instance. It thus seems clear that the selection of an *oral* pharmaceutical such as montelukast to modify the *topical* composition of DeLong et al. in order to therapeutically treat the graying of scalp hair is based purely upon hindsight with the benefit of the present disclosure. Such use of hindsight bias to construct an obviousness rejection remains improper under KSR vs. Teleflex and the USPTO guidelines promulgated as a result thereof.

In view of all of the foregoing, the present rejection is improper, should be reconsidered and withdrawn. Favorable action upon all of the pending claims is solicited.

Respectfully submitted,

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